

## INTERVIEW SUMMARY

A telephonic interview was conducted on February 7, 2005. Applicants thank Examiner Morris for the courtesies extended to their representative, James K. Blodgett. Applicants requested that the Examiner reconsider the initial grouping under 35 U.S.C. § 121 of the compound claims 1-2 with the composition claims 3-4, and regroup the composition claims with method claims. The Examiner declined Applicants' request. Accordingly, Applicants request entry of the claim amendments indicated under 37 C.F.R. § 1.121(c) and consideration of the accompany remarks in response to the Office Action mailed October 12, 2004. In addition, because of the foregoing amendments, amended claims 3 and 4 are readable on the elected species.

## REMARKS

In the captioned application, claims 1-4 and 15-17 stand rejected under 35 U.S.C. § 102(a), (b), and/or (e) as being anticipated by Czekaj et al. in US 2003/0092698); Tulshian et al. in US 6,727,254; Pauls et al. in US 2002/0045613; Altenburger et al. in US 6,680,329; Ewing et al. in WO 01/07436; Bastian et al. in US 6,265,416; Chen et al. in US 5,990,109; Doll et al. in US 5,880,128; Tanga et al. in CA 127: 161747; Takefuji et al. in US 5,763,463; Konishi et al. in JP 3-181462; Shimizu et al. in CA 112:193716; Matondo et al. in J. Agric. Food Chem. 1990, 38, 1106-1109; Kirazis et al. in CA 112:138873; Sakamoto et al. in CA 108:75166; Von Bebenburg et al. in CA 93:95098; Bickel et al. in US 3,929,779; Pews et al. in US 3,804,844; Yakhontov et al. in CA 69:86786; Imperial Chemical in CA 68:59438; Clark-Lewis et al. in CA 57:23142; and Takahashi et al. in CA 51:12837.

Claims 1-4 and 15-17 also stand rejected under 35 U.S.C. § 103(a) as being unpatentable over the combined teachings of Czekaj et al., Tulshian et al., Pauls et al., Altenburger et al., Ewing et al., Bastian et al., Chen et al., Doll et al., Tanga et al., Takefuji et al., Konishi et al., Shimizu et al., Matondo et al., Kirazis et al., Sakamoto et al., Von Bebenburg et al., Bickel et al., Pews et al., Yakhontov et al., Imperial Chemical, Clark-Lewis et al. and Takahashi et al.

Claims 1-4 also stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement and the written description requirement. The Examiner contends that the instant claims contain "subject matter which was not described in the specification in such a way to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention" and "subject matter which was not described in the specification in such a way as to reasonably

convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.”

Claims 3 and 4 also stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite “for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.” The Examiner contends that claim 3 “provides for the use of treating injured mammalian nerve tissue but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass.” The Examiner also contends that the recitation of “salts” in claim 4 “makes claim 4 read on mixtures rather than specific compounds.”

Finally, claim 3 also stands rejected under 35 U.S.C. § 101 as an improper process claim because the Examiner indicates that claim 3 recites “...a use, without setting forth any steps involved in the process,...”.

Applicants have canceled claims 1-2, and 15-17, thereby obviating the Examiner’s rejections directed thereto under 35 U.S.C. § 102(a), (b), and/or (e); 35 U.S.C. § 103(a); and the Examiner’s rejections directed to claims 1-2 under 35 U.S.C. § 112, first paragraph. Nevertheless, Applicants respectfully submit that a person of ordinary skill in the art would recognize that the formation of solvates is a likely, if not an expected, result when compounds are prepared or recrystallized, in general, and in particular when solvents or solvent combinations such as ethyl acetate, water and/or methanol-water are employed in such preparations or in recrystallization, as in the captioned application. However, in order to expedite prosecution, Applicants have amended claims 3 and 4, deleting the recitation of “solvate” and “solvates,” respectively, thereby obviating the Examiner’s rejections directed thereto under 35 U.S.C. § 112, first paragraph. Applicants have also deleted the recitation of “polymorph” and “polymorphs,” in those claims.

Applicants traverse the Examiner’s rejection under 35 U.S.C. § 102(a), (b), and/or (e), and consider that none of the references cited by the Examiner anticipate claims 3 and 4. Applicants also traverse the Examiner’s rejection under 35 U.S.C. § 103(a) and consider claims 3 and 4 to be patentable over the combination of those references cited by the Examiner under 35 U.S.C. § 102(a), (b), and/or (e). In addition, Applicants traverse the Examiner’s rejection of claims 3 and 4 under 35 U.S.C. § 112, second paragraph, as well as the Examiner’s rejection of claim 3 under 35 U.S.C. § 101. Therefore, Applicants request reconsideration of the Examiner’s rejections of claims 3 and 4 under 35 U.S.C. § 102(a), (b), and/or (e); 35 U.S.C. § 103(a); 35 U.S.C. § 112, second paragraph; and 35 U.S.C. § 101 pursuant to the arguments presented below.

In the rejection of Applicants' claims 3 and 4 under 35 U.S.C. § 102(a), (b), and/or (e), the Examiner contends that the instant claims are anticipated by compounds disclosed in Czekaj et al., Tulshian et al., Pauls et al., Altenburger et al., Ewing et al., Bastian et al., Chen et al., Doll et al., Tanga et al., Takefuji et al., Konishi et al., Shimizu et al., Matondo et al., Kirazis et al., Sakamoto et al., Von Bebenburg et al., Bickel et al., Pews et al., Yakhontov et al., Imperial Chemical, Clark-Lewis et al. and Takahashi et al. Applicants respectfully remind the Examiner that in order “[f]or a prior art reference to anticipate in terms of 35 U.S.C. § 102, every element of the claimed invention must be identically shown in a single reference.” In re Bond, 15 USPQ2d 1566, 1567 (Fed. Cir. 1990). Accordingly, Applicants note that claims 3 and 4 are directed to a pharmaceutical composition “for the treatment of injured mammalian nerve tissue.” In contrast, the afore-mentioned references cited by the Examiner fail to teach a pharmaceutical composition for the treatment of injured mammalian nerve tissue. While these references may teach compounds that fall within the scope of the structure represented by the formula recited in Applicants’ claims 3 and 4, there is no mention of those compounds combined in the form of a pharmaceutical composition, including a pharmaceutical composition “for the treatment of injured mammalian nerve tissue,” as required by Applicants’ claims 3 and 4. Simply, each of Czekaj et al., Tulshian et al., Pauls et al., Altenburger et al., Ewing et al., Bastian et al., Chen et al., Doll et al., Tanga et al., Takefuji et al., Konishi et al., Shimizu et al., Matondo et al., Kirazis et al., Sakamoto et al., Von Bebenburg et al., Bickel et al., Pews et al., Yakhontov et al., Imperial Chemical, Clark-Lewis et al. and Takahashi et al. is silent to the inclusion of the compounds recited in Applicants’ claims 3 and 4 in the claimed pharmaceutical composition. Therefore, Applicants respectfully submit that the afore-mentioned references cited by the Examiner, and the compounds disclosed therein, fail to teach each limitation of claims 3 and 4. As such, these references are incapable of anticipating Applicants’ claims 3 and 4.

In the rejection of Applicants’ claims 3 and 4 under 35 U.S.C. § 103(a), the Examiner contends that the instant claims are unpatentable over the combined teachings of Czekaj et al., Tulshian et al., Pauls et al., Altenburger et al., Ewing et al., Bastian et al., Chen et al., Doll et al., Tanga et al., Takefuji et al., Konishi et al., Shimizu et al., Matondo et al., Kirazis et al., Sakamoto et al., Von Bebenburg et al., Bickel et al., Pews et al., Yakhontov et al., Imperial Chemical, Clark-Lewis et al. and Takahashi et al. The Examiner asserts that these “references generically embrace the instant compounds,” “that one having ordinary skill in the art would have found the claimed compounds prima facie obvious,” that “[t]he requisite motivation for arriving at the claimed compounds stems from the fact that they fall

within the generic class of compounds disclosed by the references,” and that “one having ordinary skill in the art would have been motivated to prepare any of the compounds embraced by the disclosed generic formula, including those encompassed by the claims” (emphasis added). However, Applicants’ claims 3 and 4 are directed to pharmaceutical compositions “for the treatment of injured mammalian nerve tissue,” not to compounds *per se*. Further, and as stated above in Applicants’ response to the Examiner’s rejections under 35 U.S.C. § 102(a), (b), and/or (e), none of the afore-mentioned references cited by the Examiner teach a pharmaceutical composition for the treatment of injured mammalian nerve tissue. Those references are silent to the inclusion of the compounds recited in Applicants’ claims 3 and 4 in the claimed pharmaceutical composition. Therefore, Applicants believe that the Examiner’s assertion that it would have been obvious to combine the cited references to arrive at Applicants’ invention defined by claims 3 and 4 is unfounded because such an assertion must be accompanied by the required showing as to where the cited references disclose the desirability of making the pharmaceutical composition that is Applicants’ invention as defined by claims 3 and 4. Establishing that the prior art would have suggested the claimed invention requires an underlying factual showing of suggestion, teaching, or motivation to combine the prior art references and is an “essential evidentiary component of an obviousness holding” under section 103(a). *Brown and Williamson Tobacco*, 229 F.3d at 1124-25 (*quoting C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1351-52 (Fed.Cir.1998)). There is simply no suggestion, teaching, or motivation that the compounds disclosed in the cited references could be included in a pharmaceutical composition for the treatment of injured mammalian nerve tissue. Therefore, and contrary to the Examiner’s contention, a person of ordinary skill in the art would not have been motivated to combine the cited references to arrive at Applicants’ invention as defined by claims 3 and 4. As such, these references are incapable of rendering obvious Applicants’ claims 3 and 4.

In the rejection of Applicants’ claim 3 under 35 U.S.C. § 112, second paragraph, and under 35 U.S.C. § 101, the Examiner contends that the instant claim “provides for the use of treating injured mammalian nerve tissue but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass” and “results in a claim which is not a proper process claim under 35 U.S.C. 101,” respectively. The Examiner is respectfully directed to the preamble of amended claim 3 setting forth the statutory class of the invention, and reads: “A pharmaceutical composition for the treatment of injured mammalian nerve tissue,...” (emphasis added).

Accordingly, Applicants respectfully point out that claim 3 is a composition claim, and not a method nor a process claim, and is therefore not required to set forth any steps related thereto.

In the rejection of Applicants' claim 4 under 35 U.S.C. § 112, second paragraph, the Examiner contends that the recitation of "salts" therein allegedly "makes claim 4 read on mixtures rather than specific compounds." Applicants respectfully remind the Examiner that claim 4 depends from claim 3, which recites a pharmaceutical composition that includes an effective amount of the recited formula, as defined in claim 3, or a pharmaceutically acceptable salt of that formula. Claim 4, depending from claim 3, recites a Markush group that includes specific examples of those compounds falling within the scope of the formula recited in claim 3. Therefore, and implicitly, pharmaceutically acceptable salts of those specific examples recited in claim 4 are also intended to be included in the scope of the compounds recited in claim 4. Applicants have used the plural "salts" in claim 4 to properly refer to the preceding list of compounds, and therefore a plural is necessary.

The Examiner's objection appears to center on her interpretation that the plural "salts" makes "claim 4 read on mixtures." Applicants respectfully point out that claim 3, and therefore claim 4 which depends on claim 3, are open-ended claims, and refer the Examiner to Applicants' use of comprising language in claim 3, with reference to the claimed pharmaceutical composition. Thus, claim 3 recites the requirements defining its scope. However, it is to be understood that since that claim is open-ended, any composition, including any mixture, that otherwise meets the specific limitations recited in claim 3 falls within the scope of claim 3. Correspondingly, claim 4, which only further refines the definition of the compound recited in the claimed pharmaceutical composition, also includes any mixture which otherwise meets the limitations recited in claim 4. Hence, Applicants believe that the use of the plural "salts" is proper and definite. Accordingly, Applicants respectfully request that the Examiner reconsider her rejection of claim 4 on that basis.

Based on the foregoing amendments to the claims and the accompanying arguments, Applicants consider claims 3 and 4 to be in condition for allowance. Applicants respectfully request that the Examiner reconsider the pending rejections, leading to their withdrawal, and passage of the instant application to issuance.

Respectfully submitted,  
BARNES & THORNBURG



James K. Blodgett  
Agent for Applicants  
Reg. No. 48,480

JKB:glt  
Indianapolis, IN  
(317) 231-7401